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510(k) Summary
K12_____

AUG 6 2012

(1) Submitter:
Heart Sync, Inc.
5643 Plymouth Road
Ann arbor, MI 48105
TEL 800-828-4681
FAX 734-213-5640
Contact: Stephen Shulman, President
Date prepared: January 27, 2012

(2) The name of the device: Pediatric Physio AED Pad; Pediatric Philips AED Pad
Common or usual name: Single Use Defibrillator Pad for AED
Classification name:/Product Code automated external defibrillators (non-wearable) Code MKJ, 21CFR 870.5310

(3) Predicate devices: K022732 Medtronic/Physio-Control Infant/Child Reduced Energy Electrodes; K003819, Defibrillator Electrodes/Pads PHILIPS - Forerunner 2 Pediatric Defibrillator Pads, K081442 Heart Sync, HEART SYNC PEDIATRIC, MODEL PED-100.

(4) Description of the device: These are single use, non-sterile, self stick defibrillator electrodes packaged in pairs. Effective electrode area = Conductive Area: 92 Sq. cm. They are radiotranslucent. They come in two connector styles to match the specific defibrillator. The construction and materials employed are similar to the predicates. The patient contact material is a conductive adhesive hydrogel identical to the material used in the predicate devices. These pads meet the AAMI Standard ANSI/AAMI DF80:2003 and the connectors meet the FDA performance standard for touch proof ECG connectors.

(5) Statement of the intended use of the device: Indicated for use to treat patients in cardiopulmonary arrest who are unconscious, without a pulse and not breathing spontaneously. They should only be used by personnel who have been trained in its operation. Used to deliver lower-energy therapy to children from 1 year of age to 8 years or up to 55 lbs (25kg). DO NOT DELAY THERAPY IF YOU ARE NOT SURE OF EXACT AGE OR WEIGHT.

(6) This device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate devices. The defibrillator pads meet the AAMI and FDA performance standards for this type of device.

(7) Discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence:
Bench testing summary: Various different lots containing multiple samples each were subjected to the AAMI tests for DC offset, offset instability, AC small signal impedance, AC large signal impedance, defibrillator overload. All units passed these tests. The same testing routine was applied to a 42 month accelerated age shelf life test. All units passed the tests. Biocompatibility testing was performed on the patient contact material Hydrogel. The material passed biocompatibility testing. Compliance with the FDA performance standard was verified by inspection of the connectors. (Connectors must be "touch-proof."). Performance testing on the attenuator system for both types of pads was performed and testing compared performance directly with the attenuator predicates showing excellent correlation of results.

(8) Conclusion: Based on the results of the nonclinical tests (that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device) we conclude that these defibrillator pads are as safe and effective as the predicates identified in paragraph (3). Furthermore, the materials and construction methods are identical to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 6 2012

Heart Sync, Inc.
c/o Mr. Daniel Kamm
Submission Correspondent
8870 Ravello Ct
Naples, FL 34114

Re: K120536
Trade/Device Name: Heart Sync Pediatric AED Pad
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated external defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: July 27, 2012
Received: July 31, 2012

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Indications for Use

510(k) Number(if known): K12

Device Name: Heart Sync Pediatric Physio AED Pad; Heart Sync Pediatric Philips AED Pad

Indications for Use:
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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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(Division Sign-Off)
Division of Cardiovascular Devices

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